Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the January 2002 list were published in the Federal Register in July 2002.

New Approvals

NADA Number: 141-194

Trade Name:	Clinacox™ plus BMD®
Ingredients:	Diclazuril, bacitracin methylene disalicylate
Sponsor:	Schering-Plough Animal Health
Approval Date:	April 2, 2002
Status:	Over-the-counter
Route:	Oral, via feed
Species:	Growing turkeys
Drug Form:	Type A Medicated Articles to make two-way combination Type C medicated feeds.
Concentration:	Diclazuril 0.91 grams activity per pound of Type A Medicated Article; bacitracin methylene disalicylate 10, 25, 30, 40, 50, 60, or 75 grams activity per pound of Type A Medicated Article.
Indications:	For the prevention of coccidiosis caused by *Eimeria adenoeides, Eimeria gallopavonis,* and *Eimeria meleagrimitis*, for increased rate of weight gain, and improved feed efficiency.
Tolerance:	21CFR 556.185 Diclazuril: Tolerances are established for residues of parent diclazuril at 0.5 part per million in muscle, 3 parts per million in liver, and 1 part per million in skin/fat. 21CFR 556.70 Bacitracin: Tolerances for residues of bacitracin from zinc bacitracin or bacitracin methylene disalicylate in uncooked edible tissues of cattle, swine, chickens, turkeys, pheasants, and quail, and in milk and eggs is 0.5 part per million.
Withdrawal:	Zero days
Patent Number:	4,631,278 (Re: NADA 140-951) Expiration date: August 1, 2004

21CFR 558.198

NADA Number: 141-195

Trade Name:	Clinicox™ plus Flavomycin®
Ingredients:	Diclazuril, bambermycins
Sponsor:	Schering-Plough Animal Health
Approval Date:	April 2, 2002
Status:	Over-the-counter
Route:	Oral, via feed
Species:	Growing turkeys
Drug Form:	Type A Medicated Articles to make two-way combination Type C medicated feeds.
Concentration:	Diclazuril - 0.91 grams activity per pound of Type A Medicated Article; bambermycins 2, 4, or 10 grams activity per pound of Type A Medicated Article.
Indications:	For the prevention of coccidiosis caused by *Eimeria adenoeides, Eimeria gallopavonis,* and *Eimeria meleagrimitis*, and for increased rate of weight gain and improved feed efficiency.
Tolerance:	21CFR 556.185 Diclazuril: Tolerances for parent diclazuril (marker residue) have been established as follows: 0.5 part per million in muscle, 1 part per million in skin/fat, and 3 parts per million in liver. Bambermycins: Tolerances for bambermycins have not been established.
Withdrawal:	Zero days
Patent Number:	4,631,278 (Re: 140-951) Expiration date: August 1, 2004

21CFR 558.198

Supplemental Approvals

NADA Number: 140-890

This supplemental application provides for addition of a therapeutic claim for treatment of acute metritis in cattle.

Trade Name:	Excenel® RTU
Ingredients:	Ceftiofur hydrochloride
Sponsor:	Pharmacia & Upjohn Co.
Approval Date:	February 8, 2002
Status:	Prescription only
Route:	Intramuscular and subcutaneous in cattle, intramuscular in swine
Species:	Cattle excluding veal calves, swine
Drug Form:	Liquid (suspension)
Concentration:	50 milligrams per milliliter
Indications:	For the treatment of bovine respiratory disease (BRD, shipping fever, pneumonia) associated with *Mannheimia* (*Pasteurella) haemolytica*, *Pasteurella multocida* and *Haemophilus somnus*; for the treatment of acute bovine interdigital necrobacillosis (foot rot, pododermatitis) associated with *Fusobacterium necrophorum* and *Bacteroides melaninogenicus*; and for treatment of cattle, up to 14 days post-partum, for acute metritis associated with bacterial organisms susceptible to ceftiofur.
Tolerance:	21CFR 556.113 Ceftiofur: Tolerances are established for residues of desfuroylceftiofur (marker residue) in edible cattle tissues at 8 parts per million in kidney (target tissue), 2 parts per million in the liver, 1 part per million in muscle, and 100 parts per billion in milk. A tolerance for residues of ceftiofur in edible tissue of swine, poultry and sheep is not required.
Withdrawal:	2 days
Patent Number:	4,902,683 Expiration Date: February 20, 2007 5,736,151 April 7, 2015
Exclusivity:	3 years

21CFR 522.314

ANADA Number: 200-232

This supplemental application provides for the addition of the subcutaneous route of administration of oxytetracycline injection in cattle and the addition of a new class, lactating dairy cattle.

Trade Name:	Geomycin 200
Ingredients:	Oxytetracycline hydrochloride
Sponsor:	Pliva d.d.
Approval Date:	April 8, 2002
Status:	Over-the-counter
Route:	Intramuscular in swine, intramuscular or intravenous, subcutaneous (new) in cattle
Species:	Cattle, swine
Drug Form:	Liquid (solution)
Concentration:	200 milligrams per milliliter
Indications:	**Cattle:** For the treatment of pneumonia and shipping fever complex associated with *Pasteurella* spp. and *Hemophilus* spp.; infectious bovine keratoconjunctivitis (pinkeye) caused by *Moraxella bovis* ; foot rot and diphtheria caused by *Fusobacterium necrophorum;* bacterial enteritis (scours) caused by *Escherichia coli* ; wooden tongue caused by *Actinobacillus lignieresii* ; leptospirosis caused by *Leptospira pomona* ; and wound infection and acute metritis caused by strains of staphylococci and streptococci organisms sensitive to oxytetracycline. **Swine:** For the treatment of the bacterial enteritis (scours, colibacillosis) caused by *Escherichia coli* ; pneumonia caused by *Pasteurella multocida* ; and leptospirosis caused by *Leptospira pomona.* In sows as an aid in the control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *Escherichia coli.*

Tolerance: *21CFR 556.500* Oxytetracycline: Tolerances are established for the sum of residues of the tetracyclines including chlortetracycline, oxytetracycline, and tetracycline, in tissues of beef cattle, dairy cattle, calves, swine, as follows: 2 parts per million in muscle, 6 parts per million in liver, and 12 parts per million in fat and kidney.
Withdrawal: 28 days

21CFR 522.1660d

NADA Number: 121-473

This supplemental application provides for a change in status from prescription to over-the-counter.

Trade Name: Panacur®-C
Ingredients: Fenbendazole
Sponsor: Intervet, Inc.
Approval Date: March 19, 2002
Status: Over-the-counter
Route: Oral
Species: Dogs
Drug Form: Granules
Concentration: 22.2%
Indications: For use in adult dogs (including pregnant bitches) and puppies, six weeks of age or older, for the treatment and control of roundworms (*Toxocara canis, Toxascaris leonina*), hookworms (*Ancylostoma caninum, Uncinaria stenocephala*), whipworms (*Trichuris vulpis*), and tapeworms (*Taenia pisiformis*).

21CFR 520.905

NADA Number: 124-309

This supplemental application provides for the additional claim for the prevention and control of coccidiosis.

Trade Name: MGA® 100-200 plus Rumensin®
Ingredients: Melengestrol acetate, monensin sodium
Sponsor: Pharmacia & Upjohn Co.
Approval Date: February 26, 2002
Status: Over-the-counter
Route: Oral, via feed
Species: Cattle, heifers being fed in confinement for slaughter.
Drug Form: Type A Medicated Articles to make Type B and Type C medicated feeds.
Concentration: Melengestrol acetate 100 or 200 milligrams activity per pound of Type A Medicated Article, monensin sodium 20, 30, 45, 60, 80 or 90.7 grams activity per pound of Type A Medicated Article.
Indications: For increased rate of weight gain, improved feed efficiency, suppression of estrus (heat) and prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii.*
Tolerance: 21CFR 556.380 Melengestrol acetate: A tolerance of 25 parts per billion is established for residues of the parent compound in fat of cattle.
21CFR 556.420 Monensin: A tolerance of 0.05 part per million is established for negligible residues in the edible tissues of cattle and goats.
Withdrawal: Zero days

21CFR 558.342 and *558.355*

NADA Number: 125-476

This supplemental application provides for the additional claim for the prevention and control of coccidiosis.

Trade Name:	MGA® 500 plus Rumensin®
Ingredients:	Melengestrol acetate, monensin sodium
Sponsor:	Pharmacia & Upjohn Co.
Approval Date:	February 26, 2002
Status:	Over-the-counter
Route:	Oral, via feed
Species:	Cattle, heifers being fed in confinement for slaughter.
Drug Form:	Type A Medicated Articles to make Type B and Type C medicated feeds.
Concentration:	Melengestrol acetate 500 milligrams activity per pound of Type A Medicated Article, monensin sodium 20, 30, 45, 60, 80 or 90.7 grams activity per pound of Type A Medicated Article.
Indications:	For increased rate of weight gain, improved feed efficiency, suppression of estrus (heat) and prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii.*
Tolerance:	21CFR 556.380 Melengestrol acetate: A tolerance of 25 parts per billion is established for residues of the parent compound in fat of cattle. 21CFR 556.420 Monensin: A tolerance of 0.05 part per million is established for negligible residues in the edible tissues of cattle and goats.
Withdrawal:	Zero days

21CFR 558.342 and *558.355*

NADA Number: 138-792

These supplemental applications provides for 1) addition of claim for the prevention and control of coccidiosis and the complete dose range for tylosin phosphate (60 – 90 mg/head/day) when co-administered with melengestrol acetate and 2) co-administration of melengestrol acetate, monensin, and tylosin phosphate to heifers fed in confinement for slaughter when all three drugs are contained in a common Type C liquid feed.

Trade Name:	MGA® plus Rumensin® plus Tylan®
Ingredients:	Melengestrol acetate, monensin sodium, tylosin phosphate
Sponsor:	Pharmacia & Upjohn Co.
Approval Date:	February 26, 2002
Status:	Over-the-counter
Route:	Oral, via feed
Species:	Cattle, heifers fed in confinement for slaughter.
Drug Form:	Type A Medicated Articles to make Type B or Type C medicated feeds.
Concentration:	Melengestrol acetate 100 or 200 milligrams activity per pound of Type A Medicated Article, monensin sodium 20, 30, 45, 60, 80 or 90.7 grams activity per pound of Type A Medicated Article, tylosin 10, 40, or 100 grams activity per pound of Type A medicated Article.
Indications:	For increased rate of weight gain, improved feed efficiency, suppression of estrus (heat) and reduced incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Actinomyces (Corynebacterium) pyogenes*.
Tolerance:	21CFR 556.380 Melengestrol acetate: A tolerance of 25 parts per billion is established for residues of the parent compound in fat of cattle. 21CFR 556.420 Monensin: A tolerance of 0.05 part per million is established for negligible residues in the edible tissues of cattle and goats. 21CFR 556.740 Tylosin: A tolerance of 0.2 part per million is established for negligible residues of tylosin in uncooked fat, muscle, liver and kidney in cattle.
Withdrawal:	Zero days

21CFR 558.342 and *558.355*

NADA Number: 138-870

These supplemental applications provides for 1) addition of claim for the prevention and control of coccidiosis and the complete dose range for tylosin phosphate (60 – 90 mg/head/day) when co-administered with melengestrol acetate and 2) co-administration of melengestrol acetate, monensin, and tylosin phosphate to heifers fed in confinement for slaughter when all three drugs are contained in a common Type C liquid feed.

Trade Name:	MGA® plus Rumensin® plus Tylan®
Ingredients:	Melengestrol acetate, monensin sodium, tylosin phosphate
Sponsor:	Pharmacia & Upjohn Co.
Approval Date:	February 26, 2002
Status:	Over-the-counter
Route:	Oral, via feed
Species:	Cattle, heifers fed in confinement for slaughter.
Drug Form:	Type A Medicated Articles to make Type B or Type C medicated feeds.
Concentration:	Melengestrol acetate 500 milligrams activity per pound of Type A Medicated Article, monensin sodium 20, 30, 45, 60, 80 or 90.7 grams activity per pound of Type A Medicated Article, tylosin 10, 40, or 100 grams activity per pound of Type A medicated Article.
Indications:	For increased rate of weight gain, improved feed efficiency, suppression of estrus (heat) and reduced incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Actinomyces (Corynebacterium) pyogenes*.
Tolerance:	21CFR 556.380 Melengestrol acetate: A tolerance of 25 parts per billion is established for residues of the parent compound in fat of cattle. 21CFR 556.420 Monensin: A tolerance of 0.05 part per million is established for negligible residues in the edible tissues of cattle and goats. 21CFR 556.740 Tylosin: A tolerance of 0.2 part per million is established for negligible residues of tylosin in uncooked fat, muscle, liver and kidney in cattle.
Withdrawal:	Zero days

21CFR 558.342 and *558.355*

NADA Number: 140-863

This supplemental application provides for an additional concentration of ractopamine hydrochloride (45 grams per pound), amending the assay limits for medicated feeds, and the addition of cautionary statements to the labeling.

Trade Name:	Paylean®		
Ingredients:	Ractopamine hydrochloride		
Sponsor:	Elanco Animal Health		
Approval Date:	February 27, 2001 and June 1, 2001		
Status:	Over-the-counter		
Route:	Oral, via feed		
Species:	Swine finishing (150 lb to 240 lb)		
Drug Form:	Type A Medicated Article to make Type B and Type C medicated feeds.		
Concentration:	9 or 45 grams activity per pound of Type A Medicated Article		
Indications:	For increased rate of weight gain, improved feed efficiency, and increased carcass leanness in finishing swine fed a complete ration containing at least 16% crude protein from 150 lb to 240 lb body weight.		
Tolerance:	21CFR 556.570 Ractopamine: A marker residue tolerance is established for ractopamine hydrochloride parent in edible tissues of swine at 0.05 part per million in muscle, and 0.15 part per million in liver, the target tissue.		
Withdrawal:	Zero days		
Patent Numbers:	4,690,951	Expiration Date:	September 1, 2004
	4,734,437		September 1, 2004

21CFR 558.4 and 558.500

Change of Sponsor Address

From: BioScience Division of Milk Specialties Co.
Illinois and Water Sts.
P.O. Box 278
Dundee, IL 60118
Drug Labeler Code 032761

To: 1902 Tennyson Lane
Madison, WI 53704